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Date: 17 Apr 2003

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Re: Prior Art of Office Action mailed 3/13/03	CC:
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Comments:

Here is a copy of the "Developers Should Link Physicians and Pharmacies" article referred to within the Office Action mailed 3/13/03.

Number of pages 4 including this page

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5/9,K/1 (Item 1 from file: 148)

DIALOG(R)File 148:Gale Group Trade & Industry DB
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07302603 SUPPLIER NUMBER: 16089824 (THIS IS THE FULL TEXT)

Fax for facts. (facsimile prescriptions)

Fitzgerald, Walter F., Jr.

Drug Topics, v138, n12, p59(1)

June 27, 1994

ISSN: 0012-6616

LANGUAGE: ENGLISH

RECORD TYPE: FULLTEXT; ABSTRACT

WORD COUNT: 872 LINE COUNT: 00075

ABSTRACT: The Drug Enforcement Administration's decision to allow the facsimile transmission of controlled-substance prescriptions may improve efficiency, but it will also help pharmacists comply with drug use review requirements. Faxed prescription requests provide documented evidence of physician instructions. Pharmacists should consider asking for written confirmation of oral authorizations for other drugs.

TEXT:

Prescriber issuance of prescriptions by telefacsimile (fax) has grown significantly over the past few years. Even greater growth will now take place as a result of new regulations from the U.S. Drug Enforcement Administration (DEA) permitting telefacsimile issuance of controlled-substance prescriptions. As pharmacists know, DEA policy has previously prohibited the facsimile issuance of prescriptions for controlled substances.

Is it efficient? One key consideration in determining the extent to which prescriptions will be accepted by fax may be that of greater efficiency. One may argue, for example, that the pharmacist will spend less time on the telephone receiving oral prescriptions. On the other hand, physicians may view issuing prescriptions by telefacsimile as less efficient-- more time-consuming than simply telephoning a pharmacy.

While greater efficiency may be possible, perhaps a more convincing reason is that a fax achieves formal "documentation" of a prescription. If a dispute arises over an oral prescription, the end result will not have to be the pharmacist's word against the prescriber's word. The same may also be said of oral changes, or oral authorizations for additional refills, on existing prescriptions.

Recent enhancement of retrospective drug use review (DUR) activities, by both government and private third-party Rx benefit programs, brings new emphasis to the issue of documentation. Think also of recent pronouncements by many state boards of pharmacy that significant effort is now being devoted to the enforcement of drug use review and patient counseling requirements. Failure to document pharmacist activities, particularly with respect to Rx's and prospective DUR, can result in serious adverse consequences, including exclusion from a provider network, loss of reimbursement, and licensure disciplinary action.

For years, pharmacists have made notations on the reverse of a prescription as a primary method of documenting events related to the Rx. Such notations, however, may not be sufficient, particularly with respect to challenges by state boards of pharmacy on the issue of valid authorization for controlled-substance dispensing.

Pharmacists repeatedly accept oral instructions or authorizations relating to previously dispensed controlled-substance prescriptions. These may be noted on the reverse side of the Rx or in the "pharmacist's comments" section of the patient profile.

But what happens if a retrospective DUR process detects questionable controlled-substance therapy based on quantity dispensed, frequency of refills, or duration of therapy? Will the written notations, whether on the prescription or in the profile, adequately respond to requests for

documentation from the Rx benefit program? And what will be the result if the prescriber disagrees with the pharmacist's written notations?

DEA regulations require the pharmacist to make a notation about any oral authorization related to previously dispensed original Rxs on the reverse of the prescription [21 C.F.R. 1306.22]. The text of this regulation provides, in pertinent part:

The prescribing **practitioner** may **authorize** additional refills of Schedule III or IV controlled substances on the original prescription through an oral authorization transmitted to the pharmacist, provided the following conditions are met:

(1) The total quantity authorized, including the amount of the original **prescription**, does not **exceed** five **refills** nor extend beyond six months from the date of issue of the original **prescription**.

(2) The pharmacist obtaining the oral authorization records on the reverse of the original prescription the date, quantity of refill, number of additional refills authorized, and initials the prescription, showing who received the **authorization** from the prescribing **practitioner** who issued the original prescription.

(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

Although recognized, this traditional method of documentation may not be adequate; written documentation, issued by the prescriber, where one or more of the above conditions (e.g., quantity is increased from original prescription) is met, may prove valuable.

Put it in writing: Now that DEA permits faxing of controlled-substance prescriptions, pharmacists should request written Rxs rather than rely on oral authorizations. By having an actual prescription, rather than a pharmacist-written note, R.Ph.s will be protected against the problem described above. However, pharmacists still need to verify that state law does not prohibit faxing of controlled-substance prescriptions. If such a prohibition exists, consider requesting written statement by fax (but not an Rx) confirming the oral authorization. This, upon its receipt, should be maintained in the pharmacy to support the written notation on the reverse of the Rx.

While the focus here has been on controlled-substance prescriptions, pharmacists should also consider requesting written confirmation of other interventions with prescribers (e.g., therapeutic duplication, drug interactions) specified for prospective drug use review. Such documentation will assist greatly in establishing the facts about the respective activities of the prescriber and the pharmacist.

Watch for a detailed explanation of the new regulations in the next column.

THE AUTHOR is associate professor, College of Pharmacy, University of Tennessee. Memphis.

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INDUSTRY CODES/NAMES: DRUG Pharmaceuticals and Cosmetics
DESCRIPTORS: Drugs--Prescribing; Drug utilization--Laws, regulations,
etc.; Facsimile transmission--Usage
PRODUCT/INDUSTRY NAMES: 8045000 (Pharmacists)
FILE SEGMENT: TI File 148

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...of refill, number of additional refills authorized, and initials the prescription, showing who received the **authorization** from the prescribing **practitioner** who issued the original prescription.

(3) The quantity of each additional refill authorized is equal...

7/9,K/19 (Item 13 from file: 16)
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04068446 Supplier Number: 45923065 (THIS IS THE FULLTEXT)
PCS expands its leadership position in M.D. connectivity with new agreement; Potential for up to 100,000 additional physicians to be connected.

Business Wire, p11081046

Nov 8, 1995

Language: English Record Type: Fulltext

Document Type: Newswire; Trade

Word Count: 611

TEXT:

SCOTTSDALE, Ariz.--(HealthWire)--Nov. 8, 1995--PCS Health Systems Inc. Wednesday announced that it has entered into agreements with Systems Plus Inc., of Mountain View, Calif., and Personalized Programming Inc. of Alachua, Fla., to develop and market "PCS Link," prescription drug management software that will enable PCS to substantially expand the base of more than 30,000 physicians who already can connect to PCS electronically.

The program will enable physicians to obtain on-line information from PCS that will help them provide new levels of patient counseling and care, make more informed prescribing decisions and better manage prescription drug therapy. The software is designed to create dramatic productivity improvements, reduce prescription errors and decrease patient inconvenience.

"PCS Link" will work as an add-on module to The Medical Manager practice management software used by physicians for billing, record keeping, referrals and insurance claims. The Medical Manager, developed by Personalized Programming and marketed by Systems Plus, is the most widely used program of its type, utilized by more than 100,000 physicians in 21,000 practices.

"PCS Link" will give physicians access to two of PCS's connectivity services: Rx Inquiry(SM) and Rx Authorization(SM). Rx Inquiry allows physicians to request complete patient drug histories on-line -- information that usually is not available to physicians if their patients take medications from other doctors.

This helps prevent adverse drug reactions from multiple medications or poor diagnoses due to inadequate understanding of drug history. Rx Inquiry also lets physicians identify patient compliance problems, such as not refilling a prescription or not getting prescriptions filled in the first place.

Rx Authorization links physicians to pharmacies and enables physicians to transmit **prescriptions** and authorize or **deny refill** requests electronically. It also lets pharmacies request permission for generic and therapeutic changes on-line.

"By aligning with the premier practice management software company, PCS has increased its lead in providing physicians, pharmacists and health plan sponsors with the benefits that electronic connectivity offers," said Kevin Moley, senior vice president, product development for PCS.

"This agreement will help us to greatly extend the reach of our services, which will in turn improve the quality and cost-effectiveness of the care that is provided to our customer's plan members and employees."

PCS already is linked electronically with more than 30,000 physicians through health information networks developed by Integrated Medical Systems (IMS). Both PCS and IMS are wholly owned subsidiaries of Eli Lilly and Co. (NYSE:LLY).

"By adding PCS's electronic connectivity capabilities to The Medical Manager, we are making the best practice management software even better," said Rick Mehrlich, president of Systems Plus. "We believe that we are

setting a new standard for the industry and adding functionality that physicians will find essential."

"The ability of physicians to obtain critical health information on-line in real time is the next wave in using the computer to improve patient care," said Mickey Singer, president of Personalized Programming. "We're excited about being on the cutting edge of this capability with PCS."

PCS provides managed pharmaceutical care for more than 56 million individuals. PCS's technology, products and services effectively link participants in the health care system to produce measurable and substantial savings in overall health care costs and improvement in quality and patient satisfaction.

Founded in 1980, Systems Plus is a privately held software publishing company specializing in marketing, distribution and support of health care information systems for physicians.

Personalized Programming Inc., headquartered near Gainesville, Fla., is the developer of The Medical Manager. Founded in 1981, the company is devoted entirely to research and development of medical practice management software.

CONTACT: PCS Health Systems, Scottsdale
Blair Jackson, 602/391-4138

or
Systems Plus Inc., Mountain View
Nanci Adams, 800/222-7701

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PUBLISHER NAME: Business Wire

COMPANY NAMES: *PCS Healthcare Sys; Personalized Programming; Systems Plus Inc.

EVENT NAMES: *380 (Strategic alliances)

GEOGRAPHIC NAMES: *1USA (United States)

PRODUCT NAMES: *7372430 (Engineering & Scientific Software)

INDUSTRY NAMES: BUS (Business, General); BUSN (Any type of business)

NAICS CODES: 51121 (Software Publishers)

SPECIAL FEATURES: COMPANY

... in the first place.

Rx Authorization links physicians to pharmacies and enables physicians to transmit **prescriptions** and authorize or **deny refill** requests electronically. It also lets pharmacies request permission for generic and therapeutic changes on-line...

7/9,K/46 (Item 2 from file: 636)

DIALOG(R) File 636:Gale Group Newsletter DB(TM)

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02916216 Supplier Number: 45930927 (THIS IS THE FULLTEXT)

DEVELOPERS SHOULD LINK PHYSICIANS AND PHARMACIES

Electronic Claims Processing Report, v3, n23, pN/A

Nov 13, 1995

ISSN: 1071-8524

Language: English Record Type: Fulltext

Document Type: Newsletter; Trade

Word Count: 1081

TEXT:

Health care vendors, application developers and clearing houses should look to the retail pharmacy industry for electronic data interchange (EDI) opportunities. Although a majority of retail pharmacies--99 percent--use EDI to process claims from third-party payers, a "new frontier" of opportunities exists for connecting physician offices with pharmacies to send prescription claims electronically, industry experts told ECPR.

The number of doctors' offices connected to pharmacies by EDI is "very small," said Klaus Hieber, director of pharmacy services at the Health Alliance Plan (HAP), a managed care provider based in Detroit, Mich. Sending electronic claims prescriptions would give physicians on-line, real-time access to "formulary" guidelines and drug utilization reviews (DURs), he said.

Doctors are encouraged by hospitals, pharmacies and insurance companies to prescribe standard or "formulary" drugs for certain treatments because of their cost effectiveness.

Certain drugs also fall under DUR status, which alerts the physician to potential adverse effects medicine may have on patients.

The instant availability of this information at the point-of-service rather than the point-of-sale would reduce the time and costs associated with pharmacy calls to doctors to straighten out miscommunications, said Hieber.

Prescription Rejects

Dom Meffe Jr., chief operating officer for Greensburg, Pa.-based Columbia Pharmacy Solutions, a wholly owned subsidiary of Columbia/HCA Healthcare Corp., said that 20 percent of prescription claims are sent back because of bad handwriting, non-compliance with formularies, duplicate therapy or excessive dosing on the part of the physician. "These errors create a waste of time and add costs to the system," he said.

"Putting [electronic connection software functions] in the prescriber's office will guarantee compliance."

The success of doctors and pharmacies using EDI to send prescription claims depends largely on the willingness of the doctors to embrace the technology, Hieber believes.

Meffe said that pharmacists are more than familiar with EDI. They're "a world ahead of the rest of the health care industry," he said.

Jerry Mizer, director of marketing for Twinsburg, Ohio-based MEDE AMERICA, said that the "Pharmacy [business] is at least a decade ahead of medical. With pharmacy, everything is on-line, real-time."

Carpe Diem

Numerous application developers are looking to this EDI market as an opportunity, and bringing new products to the market and pilot programs to the industry, such as IBM.

Integrated Systems Solutions Corp., a Big Blue subsidiary, purchased Prescribe, a software system from the Chicago, Ill.-based Walgreen Co. retail pharmacy chain.

Walgreen already is using the system and Clearwater, Fl.-based Eckerd Corp. is in the process of reviewing and evaluating the system, said Rich Coyle, director of communications for Integrated Systems.

Eckerd is a retail chain, with 1,701 drug stores in 13 states from Texas to Delaware.

Coyle said that this opportunity for connecting pharmacies and doctors is a part of the whole trend toward "people using the power of networks."

"Prime users of the Prescribe system would be national pharmacy chains who would be looking to use networks to get greater efficiency in their operations," he said.

HAP and Columbia

Other evidence of vendor interest in this market can be found from California to the East Coast.

In two days, Detroit's HAP will launch a pilot program connecting 10 of its physician offices to the plan's participating pharmacies. The offices will be connected using Fort Lauderdale, Fla.-based ProxyMed's pharmacy management software program, ProxiScript.

Columbia will choose a managed care organization by the end of the month for its pilot program to allow physicians to submit prescription drug orders and refill authorizations electronically for both financial and clinical transactions. MEDE AMERICA is providing the electronic switching for the pilot.

Meanwhile, the National Wholesale Druggists' Association (NWDA) Service Corp. is allying with Sterling Software Inc.'s Network Services Division. Dublin, Ohio-based Sterling will develop information sourcing and delivery systems for NWDA HEALTHCOM members, which include major pharmaceutical manufacturers and wholesalers.

Scottsdale, Ariz.-based PCS Health Systems Inc. entered into an agreement last week with Mountain View, Calif.-based Systems Plus Inc. and Alachua, Fla.-based Personalized Programming Inc. to develop and market PCS Link, a **prescription drug** management software. PCS Link will give physicians access to PSC's Rx Inquiry and Rx Authorization. Rx Inquiry allows physicians to request complete patient **drug** histories on-line. Rx Authorization links physicians to pharmacies and enables physicians to transmit **prescriptions** and authorize or **deny** **refill** requests electronically.

Pilot Programs

Columbia's pilot with MEDE will be evaluated after about six months, says Meffe. "We will know by then if we're making any impact," he said.

Mizer believes the pharmacy market is saturated with vendors and nearly exhausted as far as electronically connecting it to payers. MEDE has made a strategic decision not to pursue a share. It is concentrating instead on connecting physicians to pharmacies.

Columbia/HCA is one of the nation's largest providers of health care services, with 325 hospitals and more than 100 outpatient surgery centers in 36 states, England and Switzerland.

Connecting doctor's offices to pharmacies via EDI is a "paradigm shift," Meffe said, but unlike the automobile industry, people won't lose their jobs.

ProxyMed will install ProxyScript in the 10 HAP participating offices. Having the physician connected to the pharmacy saves the doctor, the pharmacist and even the patient unneeded hassles, Hieber said.

The ProxiScript software allows physicians to access pharmacy-related patient data at the physician's office, screen for appropriate medication and electronically generate and transmit prescriptions through ProxyMed's computerized health care information network to local pharmacies. The patient isn't burdened with finding out a drug isn't covered by his insurance at the pharmacy, he said. Pharmacists and physicians don't waste time and money talking on the phone to clear up errors, Hieber said.

ProxyMed

In addition to ProxyScript, ProxyMed will provide HAP with ProxyNet, a network connecting physicians and pharmacies; RXReceive, software in the pharmacy; and its Clinical Command Center, the software setup for managed care organizations.

HAP has 500,000 enrolled members through nearly 3,500 physicians. It also operates 32 medical centers and 35 hospitals throughout Michigan.

Jack Guinan, president of ProxyMed, didn't place a dollar value on prescriptions handled during the pilot, but told us it would be in the hundreds of thousands of dollars.

Connecting physicians and pharmacists is "very advantageous for the managed care environment," he said. "Cost containment helps managed care environments, private physicians and pharmacies." (Columbia Pharmacy, 412/838-9669; HAP, 810/552-7853; MEDE, 216/425- 3241; NWDA, 703/787-0000; ProxyMed, 305/473-1001; Sterling Software, 614/793-4020; Integrated Systems Solutions, 914/288-3295.)

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INDUSTRY NAMES: BANK (Banking, Finance and Accounting); BUSN (Any type of business); CMPT (Computers and Office Automation)

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Pilot Programs

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Set	Items	Description
S1	541596	(PRESCRIPTION? OR DRUG? OR MEDICATION? OR MEDICAMENT? OR P-HARMACEUTICAL?) (S) (REFILL? 5N (DENY OR DENIAL OR REFUS? OR - REJECT? OR WITH()HOLD OR SUSPEND? OR DECLIN? OR DISALLOW? OR - PREVENT? OR DEPRIV? OR DISAFFIRM?))
S2	218824	(PRESCRIPTION? OR DRUG? OR MEDICATION? OR MEDICAMENT? OR P-HARMACEUTICAL?) (3N) (REFILL? 5N (DENY OR DENIAL OR REFUS? OR REJECT? OR WITH()HOLD OR SUSPEND? OR DECLIN? OR DISALLOW? OR - PREVENT? OR DEPRIV? OR DISAFFIRM?))
S3	25	(PRESCRIPTION? OR DRUG? OR MEDICATION? OR MEDICAMENT? OR P-HARMACEUTICAL?) (N) (REFILL? (3N) (DENY OR DENIAL OR REFUS? OR REJECT? OR WITH()HOLD OR SUSPEND? OR DECLIN? OR DISALLOW? OR PREVENT? OR DEPRIV? OR DISAFFIRM?))
S4	140	(PRESCRIPTION? OR DRUG? OR MEDICATION? OR MEDICAMENT? OR P-HARMACEUTICAL?) (S) (REFILL? (5N) (DENY OR DENIAL OR REFUS? OR REJECT? OR WITH()HOLD OR SUSPEND? OR DECLIN? OR DISALLOW? OR PREVENT? OR DEPRIV? OR DISAFFIRM?))
S5	103	(PRESCRIPTION? OR DRUG? OR MEDICATION? OR MEDICAMENT? OR P-HARMACEUTICAL?) (S) (REFILL? (3N) (DENY OR DENIAL OR REFUS? OR REJECT? OR WITH()HOLD OR SUSPEND? OR DECLIN? OR DISALLOW? OR PREVENT? OR DEPRIV? OR DISAFFIRM?))
S6	63	(PRESCRIPTION? OR DRUG? OR MEDICATION? OR MEDICAMENT? OR P-HARMACEUTICAL?) (3N) (REFILL? (3N) (DENY OR DENIAL OR REFUS? -

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S7	73	RD S5 (unique items)
S8	45	RD S6 (unique items)
S9	95	RD S4 (unique items)

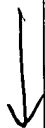
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-	1276	600/300.ccls.	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2003/03/03 15:18
-	844	700/231-242.ccls.	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2003/03/03 15:22
-	1621	235/382-383.ccls.	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2003/03/03 15:37
-	1	700/221-222, 231-242.ccls.	USPAT; US-PGPUB; EPO; JPO; DERWENT; IBM_TDB	2003/03/03 15:37
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-	24	((automat\$4 or machine or processor) NEAR3 (dispens\$4 or filling) NEAR3 (prescription or medication or drug)) SAME (authorize or authorization or deny or denial or confirm\$6 or verif\$8)	USPAT; EPO; JPO; DERWENT; IBM_TDB	2003/03/05 09:46
-	0	((dispens\$4 or filling) NEAR3 (prescription or medication or drug)) SAME ((authorize or authorization or deny or denial or confirm\$6 or verif\$8) NEAR3 (refill))	USPAT; EPO; JPO; DERWENT; IBM_TDB	2003/03/05 09:47

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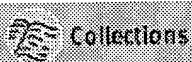
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5 articles matched your search.

- ☒ 1. **Considered** Rite Aid Restyles Bay Area Drugstores / East Coast chain to standardize 113 Thrifty Payless units; Emert, Carol; San Francisco Chronicle, San Francisco, Calif.; Feb 6, 1998; pg. D.1
- ☐ 2. JURY PROCESS BEGINS IN TUFFREE TRIAL; [SIMI VALLEY Edition]; Michael Coit Daily News Staff Writer, Daily News, Los Angeles, Calif.; May 15, 1996; pg. SV.1
- ☐ 3. LIMITS SOUGHT ON TUFFREE JURY POOL; [CONEJO VALLEY Edition]; Michael Coit Daily News Staff Writer, Daily News, Los Angeles, Calif.; Apr 30, 1996; pg. TO.3
- ☐ 4. DEFENSE WANTS SIMI, MOORPARK RESIDENTS BARRED FROM JURY POOL; [SIMI VALLEY Edition]; Michael Coit Daily News Staff Writer, Daily News, Los Angeles, Calif.; Apr 26, 1996; pg. SV.4
- ☒ 5. **Considered** Full-price drugs jolt insurance subscribers; [City Edition]; Michael Rezendes, GLOBE STAFF; Boston Globe (pre-1997 Fulltext), Boston, Mass.; Dec 6, 1992; pg. 46

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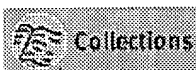
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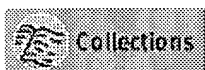
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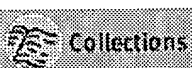
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